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EXAMINER

KAPUSHOC, STEPHEN THOMAS

ART UNIT	PAPER NUMBER
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1634

MAIL DATE	DELIVERY MODE
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03/04/2009

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/632,793

Applicant(s)

PARANHOS-BACCALA ET AL.

Examiner

Stephen Kapushoc

Art Unit

1634

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 12 December 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1, 7-36, 41-43 and 46 is/are pending in the application.
4a) Of the above claim(s) 8-15, 17-20, 22-36 and 41-43 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 7, 16 and 21 is/are rejected.
- 7) ☒ Claim(s) 46 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Claims 1, 7-36, 41-43 and 46 are pending.
Claims 8-15, 17-20, 22-36, and 41-43 remain withdrawn.
Claims 1, 7, 16, 21, and 46 are examined on the merits.

Please note: The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 12/12/2008 has been entered.

This Office Action is in reply to Applicants' correspondence of 12/12/2008. Applicants' remarks and amendments have been fully and carefully considered but are not found to be sufficient to put this application in condition for allowance. Any rejections or objections not reiterated herein have been withdrawn in light of the amendments to the claims or as discussed in this Office Action.

This Action is **NON-FINAL**.

New Claim Objections

1. Claim 46 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

***Maintained Claim Rejections - 35 USC § 102
As necessitated by amendments to the claims***

2. In the rejection of the pending claims, the required sequence elements of the claimed nucleic acids are considered an inherent property of human nuclear DNA and RNA from the plasma of human multiple sclerosis patients. Thus the cited references anticipate the claimed nucleic acid molecules even though the cited references may not specifically disclose the nucleic acid or amino acid sequences recited in the claims. Concerning the inherent nature of the claimed sequence in human genomic DNA and RNA from the plasma of human MS patients, MPEP 2112 clearly indicates that: something which is old does not become patentable upon the discovery of a new property; and that the inherent feature of a product need not be recognized in the prior art at the time of invention.

As such, in the rejection of claims under 35 USC 102 the USPTO has basis for believing that the claimed nucleic acid molecules are an inherent part of the nucleic acids referenced in the cited prior art. The MPEP in chapter 2100 states:

Where the claimed and prior art products are identical or substantially identical in structure or composition, or are produced by identical or substantially identical processes, a prima facie case of either anticipation or obviousness has been established. In re Best, 562 F.2d 1252, 1255, 195 USPQ 430, 433 (CCPA 1977). "When the PTO shows a sound basis for believing that the products of the applicant and the prior art are the same, the applicant has the burden of showing that they are not." In re Spada, 911 F.2d 705, 709, 15 USPQ2d 1655, 1658 (Fed. Cir. 1990).

In the rejection of claims, the specification does not exemplify or provide any indication that a nucleic acid molecule consisting of a sequence encoding an expression product, the sequence of which consists of the sequence set forth in SEQ ID NO: 31, is not an inherent part of the human genome. As such there is no evidence supporting any structural difference between the claimed nucleic acids and the nucleic acids of the cited prior art.

3. Claims 1, 7, 16, and 21 are rejected under 35 U.S.C. 102(b) as being anticipated by Perron et al (1997).

Perron et al teaches a sample of RNA extracted from the plasma of a human MS patient (p.7584 – RNA extraction, cDNA synthesis, and PCR amplification from MS plasma samples). The RNA extracted from the plasma of a human MS patient inherently comprises a transcript that is a sequence encoding an expression product where the expression product consists of SEQ ID NO: 31.

Regarding claims 1 and 16, as detailed above, the extracted RNA of Perron et al inherently comprises a sequence encoding an expression product that consists of SEQ ID NO: 31. With regard to claim 16, in so far as the RNA of Perron et al can be used in molecular biological methods, the RNA is a reagent.

Regarding claims 7 and 21, the extracted RNA of Perron et al inherently comprises a sequence encoding an expression product that consists of SEQ ID NO: 31, where the RNA is a transcription product. With regard to claim 21, in so far as the RNA of Perron et al can be used in molecular biological methods, the RNA is a reagent.

Response to Remarks

Applicants' have traversed the rejection of claims under 35 USC 102 as anticipated by Perron et al. Applicants argue (p.7 of Remarks) that independent claims 1 and 7 have been amended to recite the closed transitional phrases 'consisting' and 'consists' instead of 'comprising', 'comprises' and 'having'. The arguments have been fully considered but are not persuasive to allow the claims. It is noted that with regard to the requirements of the claims, the claims remain rejected over the limitations of part (ii) of claims the independent claims 1 and 7. For example, part (ii) of claim 1 requires: a nucleic acid molecule that consists of a sequence encoding an expression product,

Art Unit: 1634

the sequence of which consists of the sequence set forth in SEQ ID NO: 31. In this case, while the claim language defines the entirety of the encoded expression product, the claim language is not in fact limiting of the nucleic acid which encodes the expression product. For example, if human chromosome 3 encodes the polypeptide disclosed as SEQ ID NO: 31 (Table 2 of the instant specification), then human chromosome 3 is a nucleic acid that consists of a sequence encoding an expression product, the sequence of which consists of the sequence set forth in SEQ ID NO: 31. The Examiner recognizes the amendments to the claims as submitted 12/12/2008 and appreciates the difficulty in crafting claims to effectively differentiate the claimed subject matter from the prior art, and suggest the following as possible claim language that may be consistent with Applicants desired subject matter:

Claim 1. An isolated nucleic acid molecule consisting of a sequence belonging to a *gag* gene of an endogenous retrovirus selected from the group consisting of:

- (i) the sequence consisting of SEQ ID NO: 2
- (ii) a sequence consisting of an open reading frame encoding a polypeptide, wherein the polypeptide encoded in the open reading frame consists of SEQ ID NO: 31
- (iii) the sequence that is fully complementary to sequence (i) or (ii).

and

Claim 7. An isolated transcription product consisting of:

- (i) the sequence consisting of SEQ ID NO: 2
- (ii) a sequence consisting of an open reading frame encoding a polypeptide, wherein the polypeptide encoded in the open reading frame consists of SEQ ID NO: 31

The rejection as set forth is **MAINTAINED**.

4. Claims 1 and 16 are rejected under 35 U.S.C. 102(b) as being anticipated by Seifarth et al (1998).

Seifarth et al teaches an analysis of human genomic DNA digested with either BamHI or HindIII (Fig 3). Such DNA includes a nucleic acid molecule that encodes the polypeptide consisting of SEQ ID NO: 31 (considering that SEQ ID NO: 31 is encoded by SEQ ID NO: 2 which is an inherent part of the human genome, and that SEQ ID NO: 2 itself does not contain either a BamHI or HindIII restriction site; as such the sequence of SEQ ID NO: 2 would remain intact in the DNA of Seifarth et al).

Response to Remarks

Applicants have traversed the rejection of claims under 35 USC 102 as anticipated by Seifarth et al. Applicants' arguments (p.7 of Remarks) have been fully and carefully considered but are not found to be persuasive. Applicants arguments that independent claims 1 and 7 have been amended to recite the closed transitional phrases 'consisting' and 'consists' instead of 'comprising', 'comprises' and 'having' were discussed above in this Office Action.

Requirement for Information Under 37 C.F.R. 1.105

The previous Office Action set forth a Requirement for Information. Applicants' response (p.8 of Remarks of 12/12/2008) satisfies the requirement.

Conclusion

Art Unit: 1634

5. Claims 1, 7, 16, and 21 remain rejected. Claim 46 is objected to as dependent from a non-allowed independent claim.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Stephen Kapushoc whose telephone number is 571-272-3312. The examiner can normally be reached on Monday through Friday, from 8am until 5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla can be reached at 571-272-0735. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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/Stephen Kapushoc/
Art Unit 1634